



AUG 29 2006

Steven P. O'Connor
Finnegan Henderson Farabow Garrett & Dunner LLP
901 New York Ave., NW
Washington DC 20001-4413

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,868,112

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,868,112, which claims the human biologic product ReFacto® (novel procoagulant proteins) and a method of making ReFacto®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,258 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,258 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 5, 2002 (67 Fed. Reg. 5289). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (987) + 764 \\ &= 1,258 \text{ days (3.4 years)}\end{aligned}$$

Since the regulatory review period began May 23, 1995, after the patent issued (September 19, 1989), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,868,112
Granted:	September 19, 1989
Original Expiration Date ¹ :	September 19, 2006
Applicant:	John J. Toole, Jr.
Owner of Record:	Genetics Institute LLC

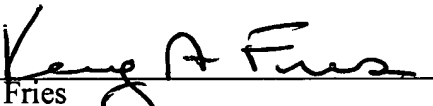
¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: Novel Procoagulant Proteins
Product Trade Name: ReFacto® (novel procoagulant proteins)
Term Extended: 1,258 days
Expiration Date of Extension: February 28, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.
By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.


Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857
Attention: Beverly Friedman
RE: ReFacto® (novel procoagulant proteins)
FDA Docket No.: 01E-0097